

**REMARKS**

**I. STATUS OF THE CLAIMS AND SUMMARY OF THE PRESENTLY CLAIMED INVENTION**

Claims 4, 16-20, 27, 29-36 and 38 are pending in the application, with claim 4 being the sole independent claim. The claims are directed towards methods of extending the dynamic range of an analyte assay, where the assay utilizes scattered light as the signaling/detection method. In particular, the presently claimed methods simplify the analysis of data provided by the light scattering particles by providing a predetermined conversion factor that can convert a set of data to a “scaled signal.” As the present claims dictate, the conversion factor is based upon the optical density of an optical filter. In the methods of the present invention, the optical density of the optical filter(s) is a quantity that is known prior to beginning the analysis or measuring any signaling, *i.e.*, the conversion factor is “predetermined.” Thus, one of the most advantageous features of the embodiments of the invention that are captured in the present claims is the reduction of user input or user calculation required to convert the data to a scaled signal.

**II. THE OFFICE ACTION OF 25 AUGUST 25 2006**

**A. WITHDRAWN REJECTIONS**

Applicants wish to thank the Examiner for withdrawing the previous rejections under 35 U.S.C. §112, second paragraph, as indicated in the Office Action of 25 August 2006.

**B. THE OBVIOUSNESS REJECTION UNDER 35 U.S.C. §103**

The Office Action of 25 August 25 2006 rejected claims 4, 18, 31-36 and 38 under 35 U.S.C. 103(a) as allegedly “being unpatentable over Phillips et al. (US 6,171,793) in view of Chenchik et al. (US 6,287,768).” *Office Action of 25 August 25 2006*, page 2. Applicants respectfully disagree with the allegations of the August 25<sup>th</sup> Office Action and request that the Examiner reconsider and withdraw the obviousness rejection in view of the remarks below.

To establish a *prima facie* case of obviousness, three criteria must be established. First, the references must teach *every* limitation of the currently claimed invention, *In re Royka*, 490 F.2d 981, 985 (C.C.P.A. 1974). Second, there must be some suggestion or motivation in the references themselves, or within the knowledge of one of ordinary skill in the art, to combine the references to arrive at the claimed invention. Lastly, there must be a reasonable expectation of success in combining the references, and this expectation of success must also be found in the references as well. *In re Vaack*, 947 F.2d 488, 493 (Fed. Cir. 1991).

In response to the arguments presented in Applicants' RCE filed 19 June 2006, the Office Action states that "Phillips et al. teach that when the results are linear the scaling factor is 200, which is a predetermined conversion factor." *Office Action of 25 August 25 2006*, page 7-8. Applicants assert, however, that Phillips fails to teach or suggest at least two elements of the present claims. First, while Phillips may briefly discuss a scale factor, Phillips does not mention or suggest the use of a predetermined scale factor. Indeed, Phillips only discusses obtaining two sets of data and having the analyst or use back-calculate a scale factor. Specifically, the disclosure in Phillips requires the user or analyst to perform a linear regression after measuring two sets of data to determine a best-fit curve between the first and second sets of data. With regards to the determination of a scale factor, Phillips states that

a probe array is scanned at a detection wavelength of 570 nm to obtain first data. Then, the array is scanned at a detection wavelength of 530 nm ...to obtain second data. ...

Then, ...an extrapolation or scale factor correlation function is calculated. Preferably, the ratio of the first and second data or count values for each scanned probe is calculated.

Then, an appropriate curve fitting algorithm is applied to the ratio values to obtain the scale factor correlation function. Assuming that the scale factor for the 530 nm (second) data is taken as unity,

the scale factor correlation function will correlate ratio as a function of 530 nm count data.

*United States Patent No. 6,171,793*, col. 10, ll. 49-57 (emphasis added). Thus, Phillips makes it clear that the user or analyst will not have any kind of scale factor prior to measuring at least two data sets. Rather, the methods of Phillips clearly require analyst or user input after at least two data sets are measured to determine a scale factor. Accordingly, one of skill in the art would not understand Phillips to teach a pre-determined scale factor as the current claims require.

In contrast, Applicants assert that the Office Action misinterprets Phillips when it alleges that Phillips teaches a predetermined scale factor. In making the obviousness rejection the Office Action appears to be relying on a passage from Phillips that states that “If the scale factor of the 530 nm curve as assumed to be unity and the curve ... is linear, the scale factor of the 570 nm curve will be approximately 200.” *United States Patent No. 6,171,793*, col. 10, ll. 27-29 (emphasis added). The use of the words “if” and “assumed” in this passage, however, clearly indicates that that the user or analyst performing the methods of Phillips will not know if the curve will be linear prior to actually performing a linear regression analysis on the data sets. Thus, Phillips does not teach that the conversion factor is predetermined.

Moreover, the above-cited passages from Phillips also highlight another difference between Phillips and the claimed invention. Specifically, the conversion factor in the present claims is based upon the optical density of one or more of the filters as required in the claims. The scale factor in Phillip, however, is based upon an after-the-fact linear regression of at least two data sets. Indeed, Phillips never mentions or suggests using the optical density of filters to determine a scale factor. Rather, when discussing a scale factor, Phillips states that the scale factor is determined by subjecting at least two data sets to an “appropriate curve fitting algorithm” *United States Patent No. 6,171,793*, col. 10, l. 53. In contrast, the methods of the present invention mandate that the conversion factor be based upon the optical density of the filter(s) used in the assays. Accordingly, Applicants assert that Phillips does not teach or even suggest each and every limitation of the claimed invention because Phillips does not teach or

suggest that the optical density of a filter may be used as a conversion factor to correlate two sets of data.

With regards to Chenchik and Bartz, which are used separately and in conjunction with Phillips to reject the pending claim under 35 U.S.C. §103, both secondary references are also silent as to (a) the use of a predetermined conversion factor and (b) the nature of the conversion factor being linked to the optical density of optical fibers. Thus, the cited references, alone or in combination fail to teach each and every limitation of the claimed invention. Accordingly, the cited references, alone or in combination fail to establish a *prima facie* case of obviousness over the presently claimed invention. Applicants request reconsideration and withdrawal of the obviousness rejections over the claimed invention.

Should the Examiner believe that further discussion of any remaining issues would advance the prosecution, he or she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

/Todd B. Buck/

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

---

Todd B. Buck, Ph.D.  
Registration No. 48,574

**57904**  
CUSTOMER NUMBER

Date: 26 February 2007